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510(k) Premarket Notification

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|------------------------------|--|
| Device Classification Name | Powered Laser Surgical Instrument |
| 510(K) Number | K200525 |
| Device Name | Medical Diode Laser Hair Removal System |
| Applicant | Weifang Mingliang Electronics CO., LTD No.13426, Yuqing Street, High-Tech District Weifang, CN 261000 |
| Applicant Contact | Li Mingliang |
| Correspondent | Beijing Believe-Med Technology Service Co., Ltd. Rm. 912, Building#15, XiYueHui, No.5, YiHe North Rd., FangShan District Beijing, CN 102401 |
| Correspondent Contact | Ray Wang |
| Regulation Number | 878.4810 |
| Classification Product Code | GEX |
| Date Received | 03/02/2020 |
| Decision Date | 05/27/2020 |
| Decision | Substantially Equivalent (SESE) |
| Regulation Medical Specialty | General & Plastic Surgery |
| 510k Review Panel | General & Plastic Surgery |
| Type | Traditional |
| Reviewed By Third Party | No |
| Combination Product | No |

Page Last Updated: 06/01/2020

1. Fortschrittliche Technologie: Gold-Zinn-Sintertechnologie,
2. Griffe: Deutschland/USA Laserbarren, 10 bar, 1000 W. 12 bar, 1200 W größere Leistung

für eine schnellere und bessere Haarentfernung. Echte schmerzlose und dauerhafte Haarentfernung mit offensichtlichen Ergebnissen. Echte schmerzlose und dauerhafte Haarentfernung mit offensichtlichen Ergebnissen.

3. Schnelle Behandlung: Nig-Spotgröße 10 * 20 mm / 15 * 25 mm / 12 * 38 mm, Frequenz 1-10 Hz, höhere Effizienz

4. Kontinuierlicher Betrieb: TEC-Kondensator Luft Wasser Halbleiter-Kühlsystem, könnte die Wassertemperatur tatsächlich konstant steuern

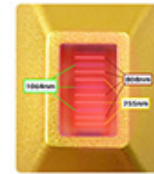
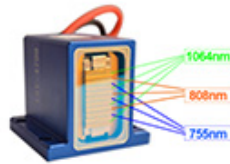
Stellen Sie bei 22-24 °C sicher, dass die Maschine 24 Stunden lang ununterbrochen arbeitet, ohne anzuhalten, auch im Sommer ohne Klimaanlage.



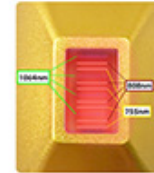
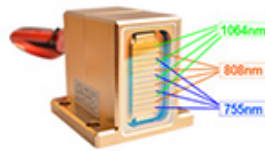
High-quality laser bars imported from Germany

1000/1200/1600ww high power

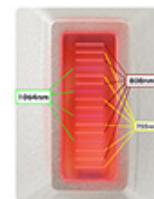
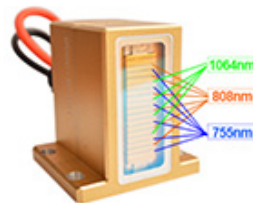
Fast hair removal



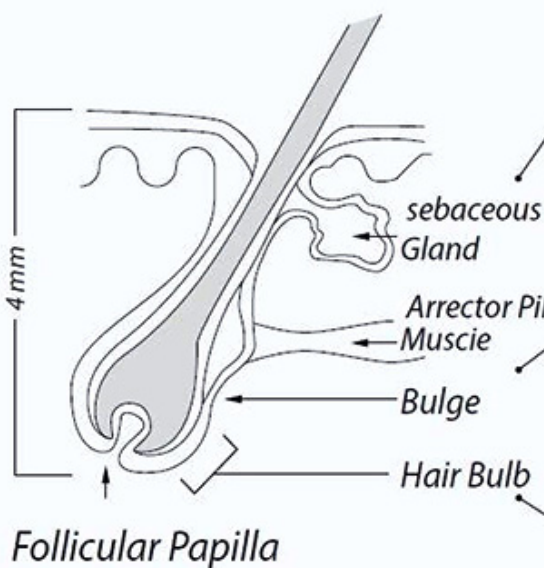
▶ 10bar
1000W



▶ 12bar
1200W



▶ 16bar
1600W



755nm

More powerful energy absorption by the melanin chromophore, making it ideal for the widest range of hair types and color

- especially light-colored and thin hair

808/810nm

Deep penetration of the hair follicle with high average power with high repetition rate for fast treatment. moderate melanin absorption level making it safe for darker skin types.

ideal for treating the arms, legs, cheeks and beard.

1064nm

low melanin absorption, focused solution for darker skin types. Offers the deepest penetration of the hair follicle, embedded hair in areas as the scalp, armpit, and pubic area.

»»Super Kühleffekt:

Saphirtemperatur: 5-3 °C. Reduzieren Sie effektiv die Schmerzen bei der Behandlung und machen Sie es möglich

»»Italien Wasserpumpe:

Besser für den Laserwasserkreis, Wärmeableitung, längere Lebensdauer.

»»Zwei Wasserfilter:

Zwei Austauschreaktionen in Lebensmittelqualität können die Wasserqualität für die Zirkulation sicherstellen



755nm



808nm



1064nm

